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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/879,665	06/12/2001	Douglas R. Daum	279.358US1	4223

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EXAMINER

OROPEZA, FRANCES P

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 03/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/879,665

Applicant(s)

DAUM, DOUGLAS R.

Examiner

Frances P. Oropeza

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 June 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 June 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5 & 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Abstract

1. The abstract of the disclosure is objected to because of it does not enable the reader to ascertain the character of the subject matter covered by the technical disclosure. More detail is needed.

The Applicant is reminded of the proper language and format for an abstract of the disclosure. The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details. The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8, 9, 12-15 and 27-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 8, "the activity signal" (line 1) and "the subject's activity" (line 3) lack antecedent basis.

In line 1 of claim 9, "the detecting" and "the activity signal" lack antecedent basis.

Claim 12 is unclear because in line 1 it appears "which detecting" should be --which the detecting--.

Claim 13 is unclear because in line 1 it appears "which adjusting" should be --which the adjusting--.

Claim 27 (line 3) and claims 28 and 29 (line 2) are unclear because it appears "a hypotension" should be --the hypotension--.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

4. Claims 1-10, 13, 17-27 and 31-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Yerich et al. (US 5562711). Yerich et al. disclose a method and apparatus for rate-responsive cardiac pacing comprising: an implantable pacemaker (10) with a pacing/control circuit (20) to provide therapy in response to combined physical and metabolic or blended demand (c 4, ll 1-23), an activity sensor circuit (21), read as the instantaneous component of the activity signal, to determine physical demand, and an impedance sensing circuit (22), read as the

Art Unit: 3762

long-term component of the activity signal, to determine the metabolic and physiological demand (c 4, ll 31-35 and c 8, ll 21-29).

As to claims 3, 4 and 18, the impedance sensing, reflecting respiratory rate, read as breathing, and tidal volume, is accomplished by measuring minute ventilation using impedance changes in the thoracic cavity (c 2, ll 12-34 and c 8, ll 33-38). It is inherent changes in tidal volume are impacted by fluid shifting to and from the lungs. Baseline values are defined for the physical and metabolic demand (c 25, ll 3-17).

As to claims 5-7, 21 and 23, the low-pass filter has a bandpass of 0.05 to 0.8 Hz (c 9, ll 4-10).

As to claims 9 and 26, the threshold values are counted to determine appropriateness of the pacing rate (c 11, l 48 – c 12, l 38).

As to claims 13 and 27, the acceleration parameter modifies the pacing rate (c 22, l 52 – c 23, l 10).

As to claim 19, electrodes are associated with the thorax (c 5, ll 46-64, c 7, ll 34-53; c 8, ll 48-52; c 9, ll 44-57).

As to claim 20, the impedance can be measured using electrodes and constant-current excitation pulses. The low-pass filtering of the impedance signal yields the respiratory rate while the high pass filtering of the same signal yields the patient's cardiac function (c 8, ll 40-52; c 8, l 66 – c 9, l 10).

5. Claims 1-8, 10-12, 17-23, 25, 27 and 31-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Combs et al. (US 5957861). Combs et al. disclose a device (10) with an

impedance monitor for discerning edema through the evaluation of respiratory rate coupled with a pacemaker system to provide therapy (c 3, ll 38-48; c 4, ll 1-4).

As to claim 4, the baseline impedance is determined with adequate sampling (c 7, ll 16-33).

As to claims 5-7 and 21-23, the low pass filter has a band-pass of 0.05 Hz to 0.5 Hz (c 7, ll 13-15).

As to claims 8, 10, 23 and 25, a movement sensor and a body position sensor can be incorporated to determine the systemic demand (c 5, ll 39-45 and c 12, ll 1-16).

As to claims 11 and 12, edema in the lungs is noted to impact blood pressure, hence creating hypotension when the pressure is low and hypertension when the pressure is high (c 8, ll 37-48).

6. Claims 1-4, 7, 8, 10-13, 17-19, 23-25, 27 and 31-35 are rejected under 35 U.S.C. 102 (e) as being anticipated by Pitts Crick et al. (US 6104949). Pitts Crick et al. disclose an implantable pulse generator system to diagnosis and treat congestive heart failure by sensing transthoracic impedance (42) and position (99) and relating these values to the baseline value (c 2, l 35 - c 3, l 9). The breathing is inherently detected based on the impedance measurement, indicating the degree of edema (c 2, ll 29-40).

As to claim 4, the baseline is determined based on averages (c 4, ll 30-34; c 5, ll 36-51).

As to claim 7, a higher frequency component of the impedance signal is analyzed (c 4, ll 40-47).

As to claim 19, electrodes are associated with thorax (c 3, ll 21-64).

7. Claims 1-4, 8, 10, 17-19 and 23-25 are rejected under 35 U.S.C. 102(e) as being anticipated by Erlebacher et al. (US 6473640). Erlebacher et al. disclose an implanted device (1) for long-term detection and monitoring of congestive heart failure. A pacemaker generates signals and obtains a dual frequency signal that can measure venous impedance and pulmonary impedance, pulmonary impedance being indicative of pulmonary edema and the associate fluid shifts (c 2, ll 37-54; c 4, ll 7-18). The pacemaker rate is increased to reduce the congestion in the lungs(c 5, ll 48-61).

As to claim 4, changes in the impedance measurements over time provide a baseline (c 4, ll 19-30).

As to claim 19, electrodes are associated with the thorax (c 5, ll 51-55; c 6, ll 20-51).

As to claims 8, 10, 23 and 25, an accelerometer may be included to determine the impact of activity and posture on the impedance measurement (c 9, l 46 - c 10, l 18).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 14-16 and 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yerich et al. (US 5562711) in view of Kieval (US 5800464). As discussed in paragraph 4 of this action, Yerich et al. disclose the claimed invention except for the pacing therapy being stepped and gradually adjusted.

Kieval teaches hyperpolarization therapy using stepped and gradual pacing for the purpose of allowing the cardiac tissue to slowly adjusting to the therapeutic energy. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used stepped and gradual pacing in the Yerich et al. system in order to avoid make or break excitation of the myocardial cells so the cardiac functioning is optimized (c 4, ll 15-39; c 6, l 54- c 7, l 3).

Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Fran Oropeza, telephone number is (703) 605-4355. The Examiner can normally be reached on Monday – Thursday from 6 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is (703) 306-4520 for regular communication and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Receptionist, telephone number is (703) 308-0858.

Frances P. Oropeza
Patent Examiner
Art Unit 3762

2/23/03



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